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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,277	AU-YOUNG ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1,2,7,8 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3-6 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of applicants election with traverse of polynucleotides, fragments, variants, expression vectors and host cells and a method of expressing the polynucleotide of a host cell. Acknowledgment is also made of applicants further election with traverse of the polynucleotides encoding SEQ ID NO:6 and the polynucleotide of SEQ ID NO:13.

The traversal of the first election is on the grounds that the claims have unity of invention. This has been considered but not found persuasive. Applicant has failed to point out the special technical feature shared by each of the polynucleotides or the polypeptides encoded therefrom. Further, the claims are not novel over the prior art as evidenced by the art rejections below. Therefore the claims lack a special technical feature which renders a special contribution over the prior art. Thus, the claims lack unity of invention because of the lack of a special technical feature which is novel in the art.

The traversal of the second election is based on section 803.04 of the MPEP which states that "up to ten independent an distinct nucleotide sequence will be examined in a single application without restriction". This has been considered but not found persuasive. Firstly, "up to 10" includes one sequence. Secondly, the PTO does not have the computer resources to commit to searching electronic databases for ten polynucleotide sequences per application. In order to best share the PTO resources over all pending applications it is necessary to restrict the number of polynucleotide sequences searches in each application. Thus, the searching of all the polynucleotide sequence in the instant application would result in an undue burden of search. The restriction requirement is deemed proper and adhered to.

Claims 1-21 are pending. Claims 1, 2, 7, 8 and 15-21, drawn to non-elected inventions, are withdrawn from consideration. Claims 3-6 and 9-14 are examined on the merits.

Priority

Acknowledgment is made of a claim to an earlier effective filing date via the provisional applications 60/155,267, 60/155,266, 60/155,227 and 60/240,034. Upon review of each of these applications it is noted that only the '034 application discloses the instant SEQ ID NO:13

encoding SEQ ID NO:6, therefore the effective priority date for the instant claims will be December 3, 1998.

Claim Objections

Claim 3 is objected to for being dependent on a non-elected invention.
Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite in the recitation of "stringent conditions". All hybridization conditions have some degree of stringency, low, moderate or high, Therefore the physical parameters which determine the specific polynucleotides which hybridize are unclear. Therefore the metes and bounds of polynucletides which fulfill the specific embodiments of the claims are unclear.

It is unclear if claim 9 encompasses polynucleotide fragments of SEQ ID NO:13 or polynucleotides comprising fragments of SEQ ID NO:13. For purpose of examination, both alternatives will be considered.

Claim Rejections - 35 USC § 101

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The instant invention is drawn to the polynucleotides encoding the CRBAP-6 polypeptide. The specification presents a sequence alignment of CRBAP-6 and bovine pulmonary SP-D (Figures

5A and 5B). The specification states that CRABP-6 and bovine SP-D share 32% sequence identity, the signal peptide sequence, the C-type lectin and the C1q domain protein sequences, four conserved cysteine residues and a collagen-like domain (page 19, line 31 to page 20, line 1). The specification states that Table 3 shows tissue-specificity and disease-association of the nucleotide sequence encoding CRBAP and that the second column indicates the tissue categories that express CRBAP as a fraction of the total tissue categories expressing CRBAP (page 20, lines 6-9). The specification states that column 3 of Table 4 lists the disease classes associated with those tissues expressing CRBAP (page 20, lines 9-10). The specification states that the CRBAP proteins are human carbohydrate associated proteins (page 18, lines 22-26) and that in particular CRBAP-6 is expressed in the liver, kidney, ovary, gut, adrenal gland and secretory epithelium (page 20, lines 14-15). The specification states that CRBAP or a fragment may be administered to a patient in the treatment of diseases listed on pages 30-32 and that polynucleotides encoding CRBAP may be used to diagnose a multitude of diseases listed on pages 42-44. The specification states that CRBAP-6 [activity] is measured by the ability of C-type lectin to bind carbohydrates, including lactose, maltose, D-mannose, D-galactose (page 56, lines 6-9). The specification states that CRBAP-6 activity in cells expressing the polynucleotides encoding CRBAP-6 can be measures by cell agglutination (page 56, lines 24-31).

The specification fails to assert a specific, substantial and credible activity for the polynucleotides encoding CRBAP-6 or the polypeptide encoded thereby, because the property of binding carbohydrate is insufficient to establish a specific, substantial and credible utility. The specification lacks teachings of the biological significance of CRBAP-6, such as particular signaling pathway, or an empirical correlation of CRBAP-6 with a specific disease state, such as a specific type of cancer. The specification provides Table 3, with coefficients representing the fraction of mRNA found in different tissues. It appears that the coefficients provided represent detection of nucleotides 168-218 in cDNA libraries derived from gastrointestinal tissue (.368), reproductive tissue (.158), urologic tissue (.105), cardiovascular tissue (.105), developmental (.105) and endocrine (.105) tissues, wherein the numerical value indicates the percentage of libraries exhibiting hybridization with a probe of nuceitdes168-218. It is noted that this value is controlled by the libraries selected for screening. Table 3 column 4 indicates that out of the libraries selected for screening 36.8% were associated with cancer, 31.5% were associated with

inflammation and 26.3% were associated with cell proliferation. It is again noted that these figures are controlled by the libraries selected for screening. Most notable, there is no indication that the libraries associated with cancer, inflammation/trauma and cell proliferation were subtracted libraries. Thus, it cannot be concluded that the detection of a polynucleotide which hybridized to the fragment of SEQ ID NO:13 were selectively expressed in such libraries to the exclusion of normal tissue.

Further, it is well known in the art that one cannot rely on a expression of a polynucleotide in various libraries to establish the expression pattern of a gene. For example, Yerushalmi et al. (Gene, 2001, vol. 265, pp. 55-60) teach that the gene for ERGL was indicated to be expressed exclusively in the prostate by EST database searching, however, Northern blot hybridization indicated that the gene was also expressed in cardiac atrium, salivary gland, spleen and selective cells in the CNS. In contrast, Caillou et al (Journal of Clinical Endocrinology and Metabolism, 2001, Vol. 86, pp. 3351-3351) reports that Northern blot analysis of different human tissues demonstrated that the LNOX gene was expressed only in the thyroid gland, while blast analysis of EST sequences indicate that the LNOX gene is expressed in non-thyroid tissues. Furthermore, Conklin et al (Briefings in Bioinformatics, 2000, vol. 1, pp. 93-99) teach that the mining of EST databases using only a single member of a protein superfamily is prone to false positive hits as some proteins contain common domains (page 95, under the heading "Pruning the False Positives"). Thus, as stated above, the presence of a polynucleotide in selected libraries is not a guarantee that the full length nucleic acid of the instant invention is represented in said libraries, nor is it a guarantee that the level of EST expression in a tissue library correlates with the level of protein or mRNA was actually present within a tissue. This data serves to demonstrate that a database hit in an EST library does not establish either an expression pattern for a gene or a function for the encoded protein. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue. Evidence of a differential expression might serve as a basis for use

of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole utility consists of its potential role as an object of use-testing." Brenner, 148 USPQ at 696. The disclosure does not present a specific, substantial and credible utility that would support the requirement of 35 U.S.C. 101.

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility..... [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Secondly, although CRBAP-6 is a carbohydrate-binding protein, a specific, substantial and credible utility cannot be ascribed to this function. Many proteins are known to bind carbohydrates, yet have total different functions. For instance,

Ecalectin has been identified as a T-cell chemo attractant (Matsumoto et al, 1998,; Hirashima et al, 2000 and 1999 and Matsushita et al 2000) versus galectin 1 which is known to induce apoptosis of T-cells and T cell leukemias (page 2, lines 22-24 and page 30, lines 8-11), and galectin 3 which is known to confer resistance to apoptosis in cultured cells (page 2, lines 27-29). These references serve to demonstrate that even among proteins binding restricted carbohydrates such as galactose, widely differing functions are exhibited by said proteins. In the instant case the CRBAP-6 protein is not defined by binding a specific carbohydrate or a specific subset of carbohydrates. Without evidence of the specific biological significance of the CRBAP-6 protein membership in the class of carbohydrate-binding proteins does not suffice to establish a specific, substantial and credible utility for said proteins because said class of proteins exhibits members having widely different utilities.

The instant situation is analogous to that which was addressed in Brenner v. Manson, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. '101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 and 9-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claim 3 is drawn in part to an isolated and purified polynucleotide encoding the fragments of SEQ ID NO:6. Claim 4 is drawn to an isolated polynucleotide variant having at least 70% sequence identity to polynucleotide encoding the polypeptide comprising SEQ ID NO:6 and fragments thereof. Claim 5 is drawn to an isolated polynucleotide which hybridizes

under stringent conditions to the polynucleotide of claim 3. Claim 6 is drawn to a polynucleotide which is complementary to the polynucleotide of claim 3. Claim 9 is drawn in part to a polynucleotide comprising fragments of SEQ ID NO:13, Claim 10 is drawn to a polynucleotide variant having at least 70% sequence identity to the polynucleotide of claim 9. Claim 11 is drawn to a polynucleotide which is complementary to the polynucleotide of claim 9. Claim 12 is drawn to an expression vector comprising at least a fragment of the polynucleotide of claim 3. Claim 13 is drawn to a host cell comprising the expression vector of claim 12. Claim 14 is drawn to a method for producing a polypeptide comprising culturing the host cell of claim 13 and recovering the polypeptide from the host cell culture

The instant claims are drawn to polynucleotides encoding fragments of SEQ ID NO:6, polynucleotides comprising fragments of SEQ ID NO:13. The instant claims are also drawn to variant nucleic acids having at least 70% sequence identity to SEQ ID NO:13, or 70% sequence identity to a fragment of SEQ ID NO:13 or 70% identity to a polynucleotide encoding SEQ ID NO:6 or 70% sequence identity to a polynucleotide encoding a fragment of SEQ ID NO:6. The claims are thus drawn to a genus of variant polypeptides encompassing sequence variants and fragments and polynucleotides which minimal comprise fragments of SEQ ID NO:13 or fragments encoding SEQ ID NO:6. The claims are not limited by the function of the polynucleotides or the function of a polypeptide encoded thereby. Thus the genus of polynucleotides claimed is highly variant encompassing polynucleotides which differ widely in structure and function from SEQ ID NO:13 and the polynucleotides encoding SEQ ID NO:6. The specification describes only SEQ ID NO:13 and the polynucleotides encoding SEQ ID NO:13. This description fails to describe the entirety of the genus claimed because the genus encompasses many members which differ in both structure and function from that of the polynucleotides encoding SEQ ID NO:6 and SEQ ID NO:13. One of skill in the art would reasonable conclude that applicant was not in possession of the claimed genus.

In the event that applicant were able to overcome, the rejection under 35 U.S.C. 101 above, the following rejection would apply:

(A) As drawn to variant polynucleotides

Claims 4-6 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding SEQ ID NO:6, does not reasonably provide enablement for variants of SEQ ID NO:6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims require that one of skill in the art be able to make and use the claimed variants or polynucleotides hybridizing to the polynucleotides which encode SEQ ID NO:6 or polynucleotides which are complementary to the polynucleotides which encode SEQ ID NO:6. The specification teaches that the complementary nucleotides need not be completely complementary to those encoding SEQ ID NO:6. Thus claim 6 is not limited to those polynucleotide which hybridize exclusively to the polynucleotides encoding SEQ ID NO:6. Further claim 5, drawn to hybridizing polynucleotides is not limited to polynucleotides which are completely complementary to those encoding SEQ ID NO:6. Thus all of the instant claims are drawn to protein variants of the polynucleotides encoding SEQ ID NO:6. The specification does not teach how to make variants of the SEQ ID NO:6 polypeptide which would have the same characteristics as SEQ ID NO:6, therefore it logically follows that the specification has not taught how to make polynucleotides encoding variants of SEQ ID NO:6 that would encode polypeptides having the same characteristics as SEQ ID NO:6. Further the specification has not taught how to use the claimed variants apart from the uses proposed for SEQ ID NO:6. One of skill in the art would be subject to undue experimentation in order to make polynucleotide variants encoding polypeptides having the same functions as SEQ ID NO:6 because structure-function relationships in the amino acid sequence of proteins is probably one of the most unpredictable areas of biotechnology. For example, as disclosed by Burgess et al. (J of Cell Bio. 111:2129-2138, 1990), replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. As disclosed by Lazar et al. Molecular and Cellular Biology 8:1247-1252 (1988) regarding transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine does not affect biological activity while replacement with serine or glutamic acid reduces the biological activity of the mitogen.. These references demonstrate that even a single amino acid substitution or what appears to be an

inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Clearly, it could not be predicted that polynucleotide, or a variant, will function as suggested. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use polynucleotide variants that encode variant polypeptides or variant polypeptide fragments. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

(B) As drawn to host cells which are comprised within a organism

The specification states that methods for introducing vectors into cells or tissues, including ex vivo stem cells, can be achieved by methods known in the art and include delivery by transfection, liposome injections or polycationic amino polymers (page 37, lines 21-26). This introduction of vectors into cells is in the realm of gene therapy and claim 13 is not enabled by the specification for the following reasons.

The instant specification does not teach how to overcome problems with in vivo delivery and expression with respect to the administration of the claimed nucleic acids or viral vectors comprising said nucleic acids. The state of the art as of the priority date sought for the instant application is that in vivo gene delivery is not well developed and is highly unpredictable. For instance Verma et al (Nature, 1997, Vol. 389, pp. 239-242) teach that the Achilles heel of gene therapy is gene delivery. Verma et al state that the ongoing problem is the inability to deliver genes efficiently and to obtain sustained expression (page 239, column 3). Eck et al (Gene-Based Therapy, In: The Pharmacological Basis of Therapeutics, Goodman and Gilman, Ed.s, 1996, pp. 77-101) teach that the fate of the DNA vector itself with regard to the volume of distribution, rate of clearance into tissues etc., the in vivo consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA the level of mRNA produced, the stability of the mRNA produced in vivo, the amount and stability of the protein produced and the proteins compartmentalization or secretory fate within the cell are primary considerations regarding effective therapy. Eck et al state that these factors differ dramatically on the vector used, the protein being produced, and the disease being treated (Eck et al bridging pages 81-82).

As of the priority date sought, it was well known in the art how to infect or transfect cells in vitro or ex vivo with viral vectors. However, using viral vectors to deliver DNA to an organism in vivo, or using infected or transfected cells to deliver nucleic acids which encode a particular protein sequence to an organism in vivo is in the realm of gene therapy, and as of the priority date sought, highly unpredictable in view of the complexity of in vivo systems. Orkin et al state ("Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy", NIH, 1995) clinical efficacy had not been definitively demonstrated with any gene therapy protocol (page 1, second paragraph). Orkin et al defines gene therapy as the transfer of DNA into recipient cells either ex vivo or in vivo (page 7, under the heading "Gene transfer"), thus encompassing the instant claims drawn to the administration of antigen presenting cells transfected or infected ex vivo. Orkin et al concludes that, "none of the available vector systems is entirely satisfactory, and many f the perceived advantages of vector systems have not been experimentally validated. Until progress is made in thee areas, slow and erratic success in applying gene transfer methods to patients can be expected" Orkin et al comment that direct administration of DNA or DNA in liposome's is not well developed and hindered by the low efficiency of gene transfer (page 8, paragraph 5). Orkin et al teach that adequate expression of the transferred genes is essential for therapy, but that data regarding the level and consistency of expression of transferred genes in animal models was unknown. Orkin et al states that in protocols not involving ex vivo infections/transfection, it is necessary to target the expression of the transferred genes to the appropriate tissue or cell type by means of regulatory sequences in gene transfer vectors. The specification does not teach a vector having a specific regulatory sequence which would direct the expression of the nucleic acids within the appropriate tissue type. The specification does not remedy any of the deficiencies or the prior art with regard to gene therapy. Given the lack of any guidance from the specification on any of the above issues pointed out by Verma or Eck or Orkin. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to make the claimed host cell in vivo.

Amendment of the claim to recited "isolated" host cell would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al (US Application 20020127576, priority to June 16, 19997).

The specific embodiments of claims 5, 6 and 9-14 are recited above.

Claim 3 is drawn in part to an isolated and purified polynucleotide encoding SEQ ID NO:6. Claim 4 is drawn to an isolated polynucleotide variant having at least 70% sequence identity to polynucleotide encoding the polypeptide comprising SEQ ID NO:6.

Ashkenazi et al disclose the cDNA encoding the PRO1182 polypeptide which is a fragment of SEQ ID NO:13 from nucleotide 24 to nucleotide 1253 and which encodes the instant SEQ ID NO:6, vectors, host cells and methods of producing polypeptide comprising culturing of said host cells (abstract).

Claims 3, 4 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Zavada et al (6,004,535).

The specific embodiments of the claims are recited above. Zavada et al disclose Sequence identifier 1 which encodes a fragment of the instant SEQ ID NO:6 from residue 53 to residue 62. The disclosed sequence is double stranded and thus fulfills the specific embodiments of claim 6.

Claims 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al (US 5,514,582)

Capon et al disclose a polynucleotide having Sequence identifier 1 which comprises a fragment of SEQ ID NO:13 from nucleotide 805 to nucleotide 823, vectors and host cells comprising said polynucleotide and a method of making a polypeptide comprising culturing the host cell comprising the polynucleotide. The sequence disclosed by Capon et al is doubled stranded and therefore fulfills the specific embodiments of claim 11

Claims 5, 6, 9, 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by the New England Biolabs Catalog (1993-1994, page 91) discloses random primers which hybridize under conditions of lowered stringency to the instant polynucleotides and which are complementary to the instant polynucleotides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D
12/27/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER